UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

MJ

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/125,005	07/30/98	CAPUT D	IVD-913

HM12/0412

PATENT DEPARTMENT
SANOFI PHARMACEUTICALS INC
9 GREAT VALLEY PARKWAY PO BOX 3026
MALVERN PA 19355

EXAMINER	
UNGAR, S	
ART UNIT	**PAPER NUMBER**
1642	9

DATE MAILED: 04/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/125,005	Applicant(s) Caput et al
	Examiner Ungar	Group Art Unit 1642

☒ Responsive to communication(s) filed on *Jan 24, 2000* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-38* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-38* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Claims 1-38 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Groups 1-9. Claims 1-5 and 33-36 are drawn to polypeptides with SEQ ID Nos 2, 4, 6, 8, 10, 13, 15, 17 19 which are assigned to Groups 1-9, respectively and are classified in Class 530, subclass 350. Claims 2-5 and 34 will be examined as they are drawn to the elected Group

Group 10-19. Claims 6-12 and 24-25 are drawn to polynucleotides with SEQ ID NO:1, 3, 5, 7, 9, 11, 12, 13, 16, 18, probes derived from said sequences as well as probes with SEQ ID NOS 21-40, a method of producing the polypeptide encoded by the sequences which are assigned to Groups 10-19, respectively and are classified in Class 536, subclass 23.1 and Class 435, subclass 69.1. Claims 6-12 will be examined as they are drawn to the elected

Group. When electing a Group for Examination, Applicant is required to identify which of probes SEQ ID NOS 21-40 correspond to the elected SEQ ID NO. The probes that correspond to the specific SEQ ID NO: will be examined with the elected group.

Group 20-29. Claims 17 and 20 are drawn to a method of making oligonucleotide primers from SEQ ID NO:1, 3, 5, 7, 9, 11, 12, 13, 16, 18 which are assigned to Groups 20-29, respectively and are classified in Class 536, subclass 23.1.

Group 30-41. Claim 18 is drawn to nucleotide primer pairs with SEQ ID Nos 20/21, 22/23, 24/25, 26/27, 28/29, 30/31, 32/29, C_{14}N/33, C_{14}N/34, C_{14}N/27, 37/38, 39/40 which are assigned to Groups 30-41, respectively and are classified in Class 536, subclass 23.1.

Group 42-51. Claim 19 is drawn to a method of using polynucleotides with SEQ ID NO:1, 3, 5, 7, 9, 11, 12, 13, 16, 18 for gene therapy which are assigned to Groups 42-51, respectively and are classified in Class 514, subclass 44.

Group 52-61. Claims 21 is drawn to a method of sequencing using polynucleotides with SEQ ID NO:1, 3, 5, 7, 9, 11, 12, 13, 16, 18 which are assigned to Groups 52-61, respectively and are classified in Class 536, subclass 23.1.

Group 62-71. Claims 22 and 37 are drawn to a method of diagnosis by hybridization with a probe derived from polynucleotides with SEQ ID NO:1,

3, 5, 7, 9, 11, 12, 13, 16, 18 which are assigned to Groups 62-71, respectively and are classified in Class 536, subclass 23.1.

Group 72-81. Claims 23, 31-32, 38 are drawn to a method of detecting aberrant syntheses or genetic abnormalities using probes derived from polynucleotides with SEQ ID NO:1, 3, 5, 7, 9, 11, 12, 13, 16, 18 which are assigned to Groups 72-81, respectively and are classified in Class 536, subclass 23.1.

Groups 82-90. Claim 26 is drawn to antibodies specific for polypeptides with SEQ ID Nos 2, 4, 6, 8, 10, 13, 15, 17 19 which are assigned to Groups 82-90, respectively and are classified in Class 530, subclass 388.1.

Groups 91-99. Claims 27 and 28 are drawn to a method for purification or detection of a polypeptide with antibodies specific for polypeptides with SEQ ID Nos 2, 4, 6, 8, 10, 13, 15, 17 19 which are assigned to Groups 91-99, respectively and are classified in Class 435, subclass 7.1 and Class 435, subclass 814.

Groups 100-108. Claim 29 is drawn to a kit comprising antibodies against polypeptides with SEQ ID Nos 2, 4, 6, 8, 10, 13, 15, 17 19 as well as visualization and quantification means which are assigned to Groups 100-108, respectively and are classified in Class 530, subclass 388.1.

Groups 109-117. Claim 30 is drawn to a method of diagnosing cancer by detecting autoantibodies with polypeptides with SEQ ID Nos 2, 4, 6, 8, 10, 13, 15, 17 19 which are assigned to Groups 109-117, respectively and are classified in Class 435, subclass 7.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-19, 30-41, 82-90 and 100-108 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions 20-29, 42-81, 91-99, and 109-107 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups 1-9 and 91-99, 109-117 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polypeptide product as claimed can be used in a materially different process such as an antigen for the production of antibodies.

The inventions of Groups 10-19 and 42-81 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polypeptide product as claimed can be used in a materially different process such as an antigen for the production of anti-idiotypic antibodies.

The inventions of Groups 82-90/100-108 and 91-99 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polypeptide product as claimed can be used in a materially different process such as an antigen for the production of anti-idiotypic antibodies.

The inventions of Groups 30-41 and 72-81 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the primer pairs as claimed can be used in a materially different process such as an in site directed mutagenesis.

Inventions 20-29 and 10-19, 30-41 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the probes can be made by recombinant methods or by machine synthesis.

The inventions of Groups 1-9 and 20-29, 42-81 are not at all related because the polypeptide of Groups 1-9 are not used in any of the methods of Groups 20-29, 42-81.

The inventions of Groups 10-19 and 91-99, 109-117 are not at all related because the polynucleotide of Groups 10-19 are not used in any of the methods of Groups 91-99, 109-117.

The inventions of Groups 82-90/100-108 and 20-29, 42-81, 109-117 are not at all related because the antibody of Groups 122-130/140-148 is not used in any of the methods of Groups 20-29, 42-81, 109-117.

The inventions of Groups 30-41 and 20-29, 42-71, 91-99, and 109-107 are not at all related because the primer pairs of Groups 30-41 are not used in any of the methods of Groups 20-29, 42-71, 91-99, and 109-107.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Groups 1-9 are further subject to election of a single disclosed species.

Claims 1 and 35 are generic to a plurality of disclosed patentably distinct species comprising polypeptides that are used in different methods with different mechanisms of action wherein the polypeptide is an (a) inhibitor of SR-p70 (claims 35 and 36), (b) an activator of SR-p70 (Claims 35-36).

target cells with different structures and functions wherein the target cells consist of (a) tumor cell, (b) auto-antibody producing cell and © IgE-producing cell.

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Patent Examiner
April 10, 2000